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Docket No. ETH1536

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants	:	Joseph H. Contiliano, et al.	
Serial No.	:	09/874,218	Art Unit: 3738
Filed	:	June 5, 2001	Examiner: W.H. Matthews
For	:	ATTACHMENT OF ABSORBABLE TISSUE SCAFFOLDS TO SCAFFOLDS FIXATION DEVICES	

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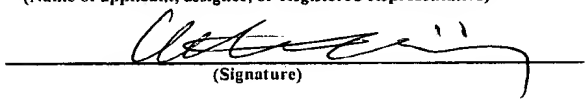
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APPEAL BRIEF

This is an appeal from the final rejection of the Examiner dated April 20, 2004, rejecting claims 1-14, all of the pending claims in the case. This Brief is accompanied by the requisite fee set forth in Rule 1.17 (f).

i. Real Party in Interest

Ethicon, Inc., a New Jersey corporation, is the real party in interest.

ii. **Related Appeals and Interferences**

None

iii. **Status of Claims**

Claims 1-14 are pending in the application. Claims 1-14 were finally rejected in an Office Action mailed on April 20, 2004 and this Appeal is taken with respect to these claims

iv. **Status of Amendments**

The application was filed on June 5, 2001 with 22 claims, two of which were independent.

The application was subject to a restriction requirement in the Office Action mailed September 10, 2002.

Applicants elected to prosecute claims 1-14 without traverse in a Response filed March 5, 2003.

Claims 15-22 were withdrawn from consideration and claims 1-14 rejected in the Office Action mailed May 30, 2003.

Applicants attempted to amend claims 1-3, 5-7, 10 and 13 and cancel claims 15-22 in the Amendment filed on September 23, 2003.

The Amendment was rejected in the Office Action mailed December 17, 2003 as not being fully responsive, in that Applicant had failed to specifically point out the support in the original disclosure for each of the newly presented claim limitations, and as the claim listing failed to comply with the revised format.

Claims 1-3, 7 and 10 were amended and claims 15-22 cancelled in the Amendment filed January 20, 2004. The claims as set out in the Appendix include the entered amendments.

Claims 1-14 were finally rejected in an Office Action mailed on April 20, 2004.

Applicants responded to the Office Action on August 19, 2004, at which time a Notice of Appeal also was filed.

An Advisory Action was mailed on September 29, 2004, indicating that the request for reconsideration by Applicants did not place the claims in condition for allowance.

v. **Summary of the Claimed Subject Matter**

Applicants are claiming a tissue scaffold implant device. The device may be used to facilitate repair or regeneration of diseased or damaged musculoskeletal tissue. The device comprises as one component a foam tissue scaffold fixedly attached to a scaffold fixation component, Page 5, lines 5-9. The tissue scaffold has a pore structure effective to facilitate tissue infiltration and growth into the foam scaffold, Page 5, lines 9-10 and Page 7, lines 20-26, for example. The fixation component comprises a tissue scaffold support component and a means for anchoring the device in the body, Page 7, line 27 – Page 8, line 9 and Figures 1-3a. The foam tissue scaffold partially encapsulates the fixation component and thus provides fixed attachment of the foam tissue scaffold to the fixation component, Page 5, lines 11- 28. As claimed in claims 2 and 13, the tissue scaffold substantially encapsulates the scaffold support component, Page 8, lines 18 – 23 and Figures 3 and 3a. Fixed attachment of the tissue scaffold to the fixation component as claimed eliminates the need for other means to maintain attachment of the scaffold component to the fixation component and thus in the body, such as sutures, staples, clips, etc. The tissue scaffold may further comprise reinforcing component, as claimed in claim 14, Page 16, line 21 - Page 17, line 26.

vi. **Grounds of Rejection to be Reviewed on Appeal**

1. Claims 1-5, 7-11, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Gresser et al.

2. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Melican et al. US 2002/0120348.

vii. **Grouping of the Claims**

As to the rejections applied against claims 1-14 under 35 U.S.C. 102(e), either over U.S. 2001/0008980 A1 (Gresser) or US 2002/0120348 A1 (Mellican), Applicants respectfully submit that claims 1 and 3-12 stand or fall together, claims 2 and 13 stand or fall together, and claim 14 stands or falls alone.

viii. Arguments

Claims 1-5, 7-11, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Gresser et al. Applicants respectfully traverse.

In order to anticipate a claim, a single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art. *Verve, LLC. V. Crane Cams, Inc., 311 F.3d 1116, 1120, 65 USPQ2d 1051 (Fed. Cir. 2002).* The reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it. *In re Spada, 911 F.2d 705,708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).* A determination of anticipation under 35 U.S.C. 102 requires a finding that each and every limitation is found either expressly or inherently in a single prior art reference. *PIN/NIP, Inc. v. Platte Chemical Co., 304 F.2d 1235, 1243, 64 USPQ2d 1344 (Fed. Cir. 2002).* A single prior art reference anticipates a claim if it expressly or inherently describes each and every limitation set forth in a claim. *Trintec Industries, Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295, 63 USPQ2d 1597 (Fed. Cir. 2002).*

Applicants respectfully submit that Gresser fails to disclose, either expressly or inherently, an implant device that comprises a foam tissue scaffold that partially encapsulates a fixation component so as to provide fixed attachment of the tissue scaffold to the fixation component.

Gresser discloses an interbody spinal fusion device (ISFD) for use as a spacer in spinal fixation. The ISFD may comprise a plurality of peripheral voids, or a central void space, which "may" be filled with a grafting material for facilitating bony development and/or spinal fusion, as well as resorption of the device by the body (0008). In particular, periosteum cells "may" be incorporated into a foam and placed into the voids (0014). Figures 4A and 4B depict an ISFD in the shape of a threaded screw. Cylindrical holes 43 and 44 are provided through the body of the ISFD orthogonal to each other and to the

screw axis, although the purpose for such holes is not disclosed. A cylindrical hole 45 is provided coaxially with the axis. Again, the purpose of the hole is not disclosed. However, as noted above, it is understood that a foam containing cells "may" be, but need not be, placed "inside" of the ISFD via the cylindrical holes. Slots 46 and 48 serve to position and retain a tool for screwing the ISFD into place. Gresser is silent, however, as to encapsulation of the ISFD by a foam tissue scaffold to provide fixed attachment of the scaffold to the ISFD.

The Office Action mailed on April 20, 2004 maintains that "Gresser discloses in Figures 4a-4b and paragraphs 8-1, 33, 38, 47 and 71 a resorbable tissue scaffold implant comprising a foam tissue scaffold component (main body of Fig 4a) and a partially encapsulated fixation component comprising threads 41 serving as anchors". The Office Action also maintains that "paragraph [0027] describes a foam tissue scaffold component encapsulating a fixation component (any of examples shown in figures 2-5)." As Applicants understand this, the Office Action is of the position that the main body of the ISFD is a foam tissue scaffold component and at the same time is encapsulated by a foam tissue scaffold component. It would appear that the Office Action is relying on the main body of the ISFD to establish each and every element of Applicants' claimed implant device, those being foam tissue scaffolds, fixation component, tissue scaffold support and partial encapsulation of the fixation component by the foam tissue scaffold. Applicants respectfully submit that such a position is untenable in view of Gresser.

It would appear that the Office Action maintains that Applicants' claimed implants are *prima facie* anticipated by Gresser, in that the ISFD of Gresser apparently is taken to be identical to Applicants' claimed implants. As noted in *Spada*, the *prima facie* case is a procedural tool which, as used in patent examination, means not only that the evidence of the prior art would reasonably allow the conclusion the Examiner seeks, but also that the prior art compels such a conclusion if the applicant produces no evidence or argument to rebut it. Upon rebuttal, the decision is made of the entirety of the record.

Applicants respectfully submit that, according to the express disclosure of Gresser, the main body of the ISFD cannot comprise foam. At paragraphs 0030, 0031 and elsewhere throughout Gresser, it is noted that the ISFD is manufactured by first molding a polymer into the shape of, e.g., a rod, and then machining the molded rod to

form the desired configuration of the ISFD [0030]. The ISFD may further be drilled to facilitate resorption of the polymer from which the device has been made [0031]. At paragraph 0037 of Gresser, it is noted that mechanical properties of the ISFD, i.e. the main body of FIG 4A, should match those of the cancellous bone of the vertebrae in regard to proportional limit stress, compression at proportion limits, etc. At paragraph 0043 it is noted that the spinal fusion device must maintain significant structural rigidity for 6-12 months. Accordingly, Applicants submit that there is no disclosure in Gresser to support the position that the main body of the ISFD of Gresser is in the form of a foam or to compel one to make such a conclusion. In fact, Applicants respectfully submit that the express teaching of Gresser would preclude one from making such a conclusion given the mechanical properties required of the ISFD.

Gresser notes that a foam scaffold containing cells may be placed "within" the machined ISFD [0014]. While the foam scaffold "may" be retained within the ISFD, Applicants respectfully submit that Glesser does not disclose, either expressly or inherently, that the internally disposed foam scaffold partially encapsulates the main body of Fig 4A. Nor does Gresser disclose or is it inherent that the internally disposed scaffold is fixedly attached to the ISFD by any means, particularly with respect to partial encapsulation of the ISFD by the foam scaffold.

Applicants respectfully submit that the main body of the ISFD according to Gresser is not a foam, as is clearly indicated above. Applicants submit that the ISFDs of Gresser (Fig 4A) are not partially encapsulated by a foam tissue scaffold component so as to fixedly attach the tissue scaffold component to the fixation component, as is required by claims 1, 3-12 and 14 of Applicants' application. With respect to claims 2 and 13 of Applicants' application, the tissue scaffold component substantially encapsulates the tissue scaffold support means. As above, Gresser fails to disclose a tissue scaffold that substantially encapsulates a tissue scaffold support component.

With respect to claim 14, Applicants respectfully submit that Gresser fails to disclose Applicants' claimed implant device where the foam scaffold component further comprises reinforcing means, as described at page 16, line 10 – page 17 line 26 of Applicants' specification. Gresser indicates that reinforcing fibers may be used in the ISFD [0009], but not in the foam tissue scaffold itself.

Based on all of the foregoing, Applicants respectfully submit that Gresser fails to disclose, either expressly or inherently, a tissue scaffold implant device comprising a foam tissue scaffold component and a fixation component partially encapsulated by the tissue scaffold component, whereby the foam scaffold is fixedly attached to the fixation component by such encapsulation. Applicants further respectfully submit that Gresser fails to disclose a scaffold support component substantially encapsulated by the tissue scaffold component, or an implant device where the tissue scaffold further comprises reinforcing means.

Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Melican et al. US 2002/0120348. Applicants respectfully traverse.

The Office Action indicates that Melican comprises fixation component 16 as shown in Fig 3, supporting foam scaffold 12 and comprising anchor means, such as sutures or staples. It is maintained that the fixation component as claimed may be the fibrous layer, which may contain staples, and/or the reinforcement mesh.

Applicants respectfully submit that Melican discloses a reinforced tissue implant that comprises a tissue scaffold component and a reinforcing component in cooperation with the tissue scaffold. As shown, structure 16 is an "optional" barrier layer and does not comprise a tissue scaffold support component or any means for anchoring the implant upon implantation. The reinforcement layer does not comprise means for anchoring the scaffold upon implantation. While Melican does disclose that fixation devices, e.g. sutures or staples, may be employed with reinforced tissue implants disclose therein, Applicants respectfully submit that devices disclosed in Melican do not disclose, either expressly or inherently, an implant comprising a tissue scaffold and a fixation component, where the fixation component comprises a tissue scaffold support and anchor means, and where the tissue scaffold partially encapsulates the fixation component, thereby provided fixed attachment of the tissue scaffold to the fixation component.

Based on the foregoing, Applicants respectfully submit that Melican fails to anticipate any of claims 1-14.

Applicants respectfully submit that the standard for anticipation is strict identify. Each and every claim element must be disclosed expressly or inherently in the prior art. Applicants respectfully submit that neither Gresser nor Melican disclose, either expressly

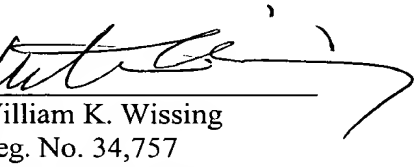
or inherently, an implantation device that includes both a foam tissue scaffold component and a fixation component, where the fixation component includes both a tissue scaffold support element and a means for anchoring the implant device upon implantation, and wherein the foam tissue scaffold partially encapsulates the fixation component, thereby providing fixed attachment of the tissue scaffold to the fixation component. Applicants further respectfully submit that claims 1-14 are patentable under 35 U.S.C. 102(e) over Gresser and Melican.

Based on all of the foregoing, Applicants respectfully request that the application be remanded with instructions to withdrawn rejections of claims 1-14 under 35 U.S.C. 102(e) over Gresser and Melican and a Notice of Allowance be issued with respect to those claims.

Please charge Deposit Account No. 10-0750/ETH1536/WKW in the name of Johnson & Johnson in the amount of $320.00, representing the cost of filing a Brief on Appeal in the above-captioned matter.

The Commissioner is hereby authorized to charge any additional fees which may be required to Account No. 10-0750/ETH1536/WKW. This Authorization is being submitted in triplicate.

Respectfully submitted,



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DATED: February 25, 2005

ix. Appendix of Pending Claims

1. (Once Amended) A tissue scaffold implant device, comprising:

a foam tissue scaffold component having a pore structure effective to facilitate tissue infiltration and growth into the foam tissue scaffold component; and

a fixation component comprising scaffold support means for supporting said foam tissue scaffold component and anchor means,

wherein the foam tissue scaffold component is fixedly attached to the scaffold fixation component via partial encapsulation of the fixation component by the foam tissue scaffold component.

2. (Once Amended) The device of claim 1 wherein the foam tissue scaffold component substantially encapsulates the scaffold support means.

3. (Once Amended) The device of claim 1 wherein the foam tissue scaffold component comprises a lyophilized polymer.

4. (Original) The device of claim 3 wherein the lyophilized polymer is bioabsorbable.

5. (Original) The device of claim 4 wherein the fixation component comprises a bioabsorbable polymer.

6. (Original) The device of claim 4 wherein the fixation component comprises a non-bioabsorbable polymer.

7. (Once Amended) The device of claim 5 wherein the lyophilized bioabsorbable polymer is selected from the group consisting of aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, tyrosine-derived polycarbonates, poly(iminocarbonates), polyorthoesters, polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes and biopolymers.

8. (Original) The device of claim 7 wherein the aliphatic polyesters are selected from the group consisting of homopolymers and copolymers of lactide, glycolide, ε-caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, δ-valerolactone, β-butyrolactone, γ-butyrolactone, ε-decalactone, hydroxybutyrate, hydroxyvalerate, 1,4-dioxepan-2-one, 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one, 2,5-diketomorpholine, pivalolactone, α,α-diethylpropiolactone, ethylene carbonate, ethylene oxalate, 3-methyl-1,4-dioxane-2,5-dione, 3,3-diethyl-1,4-dioxan-2,5-dione and 6,8-dioxabicycloctane-7-one.

9. (Original) The device of claim 8 wherein the aliphatic polyesters are elastomeric.

10. (Once Amended) The device of claim 7 wherein the lyophilized biopolymers are selected from the group consisting of hyaluronic acid, collagen, recombinant collagen, cellulose, elastin, alginates, chondroitin sulfate, chitosan, chitin, keratin and silk.

11. (Original) The device of claim 1 wherein the pore structure is open-cell.

12. (Original) The device of claim 1 wherein the pores have an average diameter of from about 10 to about 1,000 microns.

13. (Original) The device of claim 2 wherein the scaffold support means comprises through-holes.

14. (Original) The device of claim 1 further comprising a reinforcing component.

Claims 15-22 canceled.